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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC., Plaintiffs, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD. Defendants.	Civil Action No. _____ COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL RULE 11.2

JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code. Jurisdiction and venue

are based on 28 U.S.C. §§ 1331, 1338(a), 1391(b), 1391(c), 1400(b), 2201, 2202 and 35 U.S.C. § 271.

2. On information and belief, Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd. (collectively "Hanmi") have been and are engaging in activities directed toward infringement of United States Patent Nos. 5,714,504 (the "'504 patent") and 5,877,192 (the "'192 patent"), by, *inter alia*, submitting an 505(b)(2) New Drug Application designated No. 202342 seeking FDA's approval to manufacture commercially its proposed product called "Esomeprazole Strontium capsules, 20 mg and 40 mg" (hereinafter referred to as "Esomeprazole Strontium Products") containing the active ingredient esomeprazole strontium.

3. In Hanmi's notice letter entitled "Notice of Paragraph IV Certification" (hereinafter referred to as the "December 29, 2010 Letter"), Hanmi indicated that it intends to market its Esomeprazole Strontium Products before the expiration of the '504 and '192 patents.

4. Hanmi's submission of NDA No. 202342 and service of its December 29, 2010 Letter indicates a refusal to change its current course of action.

5. There has been and is now an actual controversy between Hanmi and Plaintiffs as to whether Hanmi infringes the '504 and '192 patents.

THE PARTIES

6. Plaintiff AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden. AstraZeneca AB was a corporate name change from Astra Aktiebolaget.

7. Plaintiff Aktiebolaget Hässle ("Hässle") is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

8. Plaintiff AstraZeneca LP is a limited partnership organized under the laws of Delaware having its principal place of business at Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the United States Food and Drug Administration ("FDA") for an esomeprazole magnesium formulation which it sells under the name NEXIUM®.

9. Plaintiff KBI Inc. ("KBI") is a Delaware corporation having its principal place of business at Whitehouse Station, New Jersey.

10. Plaintiff KBI-E Inc. ("KBI-E") is a Delaware corporation, having its principal place of business at Wilmington, Delaware. KBI and KBI-E have exclusive rights in the United States to patents-in-suit.

11. On information and belief, defendant Hanmi USA, Inc. ("Hanmi USA") is a company organized and existing under the laws of New Jersey having a principal place of business at 200 Park Avenue, Florham Park, New Jersey 07932-1026. On information and belief, Hanmi USA is a wholly-owned subsidiary of Hanmi Pharmaceutical Co., Ltd. On information and belief, Hanmi USA is the current holder of NDA No. 202342.

12. On information and belief, defendant Hanmi Pharmaceutical Co., Ltd. ("Hanmi Pharmaceutical") is a company organized and existing under the laws of South Korea having a principal place of business at 45 Bangi-dong, Songpa-gu, Seoul 138-724 Korea.

13. On information and belief, defendant Hanmi Fine Chemical Co., Ltd. ("Hanmi Fine Chemical") is a company organized and existing under the laws of South Korea having a place of business at 1248-8 Chungwang-Dong, Shiheung-City, Kyonggi-Do, Korea. On information and belief, Hanmi Fine Chemical is a subsidiary of Hanmi Pharmaceutical.

14. On information and belief, defendant Hanmi Holdings Co., Ltd. ("Hanmi Holdings") is a company organized and existing under the laws of South Korea having a principal place of business at 893-5 Hajeo-ri Paltan-myeon, Hwaseong-si 445-910, Korea.

15. On information and belief, Hanmi intends to manufacture and supply generic drugs for sale and use throughout the United States, including this judicial district.

16. On information and belief, Hanmi is doing business in New Jersey, has continuous and systematic contacts with New Jersey, has engaged in activities related to the subject matter of this action and is subject to personal jurisdiction in this judicial district.

FIRST CLAIM FOR RELIEF: '504 PATENT

17. AstraZeneca AB, Hässle, AstraZeneca LP, KBI and KBI-E (collectively, "Plaintiffs") reallege paragraphs 1-16, above, as if set forth specifically here.

18. The '504 patent (copy attached as Exhibit A), entitled "Compositions," was issued on February 3, 1998 to Astra Aktiebolag upon assignment from the inventors Per Lennart Lindberg and Sverker Von Unge. The patent was subsequently assigned to AstraZeneca AB. The '504 patent claims, *inter alia*, pharmaceutical formulations comprising alkaline salts of esomeprazole and methods of using formulations comprising alkaline salts of esomeprazole.

19. Plaintiff AstraZeneca AB has been and is still the owner of the '504 patent. The '504 patent will expire on February 3, 2015 and pediatric exclusivity relating to the '504 patent expires on August 3, 2015.

20. Hanmi's December 29, 2010 Letter notified Plaintiffs that Hanmi submitted a New Drug Application to the FDA under 21 U.S.C. § 355(b), seeking FDA's approval to manufacture, use, offer to sell and sell Hanmi's Esomeprazole Strontium Products.

21. In the December 29, 2010 Letter, Hanmi notified Plaintiffs that as part of its NDA it had filed a certification of the type described in 21 U.S.C. § 355(b)(2)(A)(IV) ("Paragraph IV") with respect to the '504 patent. This statutory section requires, *inter alia*, certification by the NDA applicant that the subject patent, here the '504 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(b)(3)(D)(ii)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

22. On information and belief, at the time Hanmi's December 29, 2010 Letter was served, Hanmi was aware of the statutory provisions and regulations referred to in paragraph 21, above.

23. Hanmi's December 29, 2010 Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 21 above), does not allege invalidity of claims 1-7 or 10 of the '504 patent.

24. Even where asserted, Hanmi's December 29, 2010 Letter did not provide the full and detailed statement of its factual and legal basis to support its non-infringement and/or invalidity allegations as to the '504 patent.

25. Accordingly, Hanmi's December 29, 2010 Letter fails to comply with the law, as specified in 21 U.S.C. § 355(b), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

26. Hanmi has infringed the '504 patent under 35 U.S.C. § 271(e)(2) by filing its NDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, or the use of which is claimed in this patent, prior to the expiration of the '504 patent.

27. On information and belief, Hanmi's Esomeprazole Strontium Products, if approved, will be administered to human patients in a therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Hanmi's active behest and with its intent, knowledge and encouragement. On information and belief, Hanmi will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '504 patent.

28. On information and belief, Hanmi's Esomeprazole Strontium Products are especially made or especially adapted to inhibit gastric acid secretion and for use in the treatment of gastrointestinal inflammatory disease via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the claimed esomeprazole alkaline salts and a pharmaceutically acceptable carrier. On information and belief, Hanmi is aware that its Esomeprazole Strontium Products are so made or so adapted. On information and belief, Hanmi is aware that its Esomeprazole Strontium Products, if approved, will be used in contravention of Plaintiffs' rights under the '504 patent.

29. On information and belief, the manufacture, use, offer for sale and sale of Hanmi's Esomeprazole Strontium Products directly infringe the '504 patent claims. On information and belief, Hanmi intends to obtain a marketing partner; this currently unknown and unnamed marketing partner would likewise infringe the '504 patent by offering for sale, selling and using Hanmi's Esomeprazole Strontium Products. On information and belief, Hanmi contributes to the infringement of the '504 patent through its manufacture, use, offer for sale and sale of Hanmi's Esomeprazole Strontium Products. On information and belief, Hanmi induces the infringement of the '504 patent through its manufacture, use offer for sale, and sale of Hanmi's Esomeprazole Strontium Products.

SECOND CLAIM FOR RELIEF: '192 PATENT

30. Plaintiffs reallege paragraphs 1-29 above as if set forth specifically here.

31. The '192 patent, (copy attached as Exhibit B), entitled "Method For The Treatment Of Gastric Acid-Related Diseases And Production Of Medication Using (-) Enantiomer Of Omeprazole," was issued on March 2, 1999 to Astra Aktiebolag, upon assignment from the inventors Per Lindberg and Lars Weidolf. The patent was subsequently assigned to AstraZeneca AB. The '192 patent claims, *inter alia*, methods for treatment of gastric acid related diseases by administering a therapeutically effective amount of esomeprazole and pharmaceutically acceptable salts thereof and methods for producing a medicament for such treatment.

32. Plaintiff AstraZeneca AB has been and still is the owner of the '192 patent. The '192 patent will expire on May 27, 2014 and pediatric exclusivity relating to the '192 patent expires on November 27, 2014.

33. In Hanmi's December 29, 2010 Letter, Hanmi notified Plaintiffs that, as part of its NDA, it had filed a certification of the type described in 21 U.S.C. § 355(b)(2)(A)(IV) with respect to the '192 patent. This statutory section requires, *inter alia*, certification by the NDA applicant that the subject patent, here the '192 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(b)(3)(D)(ii)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

34. On information and belief, at the time Hanmi's December 29, 2010 Letter was served, Hanmi was aware of the statutory provisions and regulations referred to in paragraph 33 above.

35. Hanmi's December 29, 2010 Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 33 above), does not allege non-infringement of claims 12-22 of the '192 patent.

36. Even where asserted, Hanmi's December 29, 2010 Letter did not provide the full and detailed statement of its factual and legal basis to support its non-infringement and/or invalidity allegations as to the '192 patent.

37. Accordingly, Hanmi's December 29, 2010 Letter fails to comply with the law, as specified in 21 U.S.C. § 355(b), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

38. By not addressing non-infringement of claims 12-22 of the '192 patent in its December 29, 2010 Letter, Hanmi admits that its Esomeprazole Strontium Products meet all limitations of claims 12-22 of the '192 patent.

39. Hanmi infringed the '192 patent under 35 U.S.C. § 271(e)(2) by filing its NDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, or the use of which is claimed in this patent, prior to the expiration of the '192 patent.

40. On information and belief, Hanmi's Esomeprazole Strontium Products, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related diseases by inhibiting gastric acid secretion.

41. On information and belief, such administration will decrease interindividual variation in plasma levels (AUC) during such treatment.

42. On information and belief, such treatment will increase average plasma levels (AUC) per dosage unit.

43. On information and belief, such treatment will effect a pronounced increase in gastrin levels in slow metabolizers during such treatment.

44. On information and belief, such treatment will effect decreased CYP1A induction in slow metabolizers during such treatment.

45. On information and belief, such treatment will elicit an improved antisecretory effect during such treatment.

46. On information and belief, such treatment will elicit an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief during such treatment.

47. On information and belief the amount to be administered will be between about 20 mg and about 40 mg total daily dose during such treatment.

48. On information and belief, this administration will occur at Hanmi's active behest and with its intent, knowledge and encouragement.

49. On information and belief, Hanmi will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '192 patent.

50. On information and belief, Hanmi's Esomeprazole Strontium Products are especially made or especially adapted to inhibit gastric acid secretion and for use in the treatment of gastrointestinal inflammatory disease via the administration of a therapeutically effective amount of a pharmaceutical formulation containing an alkaline salt of esomeprazole. On information and belief, Hanmi is aware that its Esomeprazole Strontium Products are so made or so adapted.

51. On information and belief, Hanmi is aware that its Esomeprazole Strontium Products, if approved, will be used in contravention of Plaintiffs' rights under the '192 patent.

52. On information and belief, the manufacture, use, offer for sale and sale of Hanmi's Esomeprazole Strontium Products directly infringe the '192 patent claims. On information and belief, Hanmi intends to obtain a marketing partner; this currently unknown and unnamed marketing partner would likewise infringe the '192 patent by offering for sale, selling

and using Hanmi's Esomeprazole Strontium Products. On information and belief, Hanmi contributes to the infringement of the '192 patent through its manufacture, use, offer for sale and sale of Hanmi's Esomeprazole Strontium Products. On information and belief, Hanmi induces the infringement of the '192 patent through its manufacture, use, offer for sale and sale of Hanmi's Esomeprazole Strontium Products.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Hanmi's NDA under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)) for the drug product "Esomeprazole Strontium capsules, 20 mg and 40 mg" must be later than August 3, 2015, the expiration date of the last patent in suit, including pediatric exclusivity relating to the patent, that is infringed;

(b) A judgment declaring that the '504 and '192 patents remain valid, remain enforceable and have been infringed by defendant Hanmi;

(c) A judgment declaring that Hanmi has not complied with the requirements of 35 U.S.C. § 271(e)(2), 21 U.S.C. § 355(b)(2)(A)(IV), 21 U.S.C. § 355(j)(2)(B)(iv), 21 C.F.R. § 314.94 and 21 U.S.C. § 314.95;

(d) A judgment that Hanmi's defenses and claims for relief are limited to those presented in Hanmi's December 29, 2010 Letter;

(e) A judgment that Hanmi admits to infringement of '192 claims 1-6, 8-18 and 20-23 and '771 claims 1-12 by failing to address non-infringement of those claims in its December 29, 2010 Letter;

(f) A judgment that Hanmi's intentional failure to comply with the requirements of 35 U.S.C. § 271(e)(2), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), 21 U.S.C. § 355(b)(3)(D)(ii), 21 C.F.R. § 314.94 and 21 U.S.C. § 314.95 is exceptional;

(g) An permanent injunction against any infringement by Hanmi of the '504 and '192 patents;

(h) Attorneys' fees in this action under 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such other relief as this Court may deem proper.

Respectfully Submitted,

Dated: February 9, 2011

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of the following actions:

ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC. v. SANDOZ, INC. v. MERCK & CO., INC., 3:09-cv-00199-JAP-TJB (District of New Jersey).

ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC. v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., 3:09-cv-05404-JAP-TJB (District of New Jersey).

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC. v. MERCK SHARP & DOHME CORP., 3:10-cv-00683-JAP-TJB (District of New Jersey).

ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC. v. SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, INC., and SUN PHARMACEUTICAL INDUSTRIES, LTD., 3:10-cv-01017-JAP-TJB (District of New Jersey).

Dated: February 9, 2011

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